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David W. Hibler

41,071

(Reg. No.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|----------------------|--------------------------------|-----------|
| Appellant(s): | Donoho <i>et al.</i> | Group Art Unit: | 1646 |
| Application No.: | 09/733,387 | Appeal No.: | 2004-1103 |
| Filed: | 12/07/2000 | Examiner: | R. Li |
| Title: Novel Human Membrane Proteins and Polynucleotides Encoding the Same | | Atty. Docket No.: LEX-0104-USA | |

REQUEST FOR REHEARING UNDER 37 C.F.R. § 1.197(b)

Mail Stop Appeal Brief - Patents
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Appellants acknowledge the receipt of the Decision on Appeal ("the Decision") in the above-referenced case, mailed on June 30, 2004, which has been carefully reviewed and studied. Appellants herein request rehearing, as discussed in detail below.

As set forth in 37 C.F.R. § 1.197(b), the time limit for filing a request for rehearing is "within two months from the date of the original decision". The present request for rehearing is therefore timely filed, and Appellants believe no fees are due in connection with this request. However, the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

REQUEST FOR REHEARING

As set forth in 37 C.F.R. § 1.197(b), "(t)he request for rehearing must state with particularity the points believed to have been misapprehended or overlooked in rendering the decision". Appellants respectfully submit that the Board failed to consider one credible, specific, substantial, and well-established utility, as set forth in the Appeal Brief in the present case. Specifically, Appellants respectfully point-out that pages 4-8 of the present Appeal Brief describe, *inter alia*, evidence of record that clearly establishes that the present application and claims meet the administrative requisites outlined in Example 10 of the Revised Interim Utility Guidelines Training Materials. Specifically, the present Appeal Brief describes: 1) Sequences sharing between 90-100% percent identity at the protein level over the entire length of the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank); 2) That the identified sequences have been annotated by third party scientists *wholly unaffiliated with Appellants* as "Homo sapiens similar to G protein-coupled receptor 56" (GenBank accession number XM_169439; see **Exhibit A** of the Appeal Brief), "Homo sapiens GPR97 mRNA for G protein-coupled receptor 97" (GenBank accession number AB049169; see **Exhibit B** of the Appeal Brief), "Novel G protein-coupled receptor protein and DNA thereof" (GenBank accession number BD170396; see **Exhibit C** of the Appeal Brief), "Homo sapiens similar to G protein-coupled receptor 56 (GPR97)" (GenBank accession number NM_170776; see **Exhibit D** of the Appeal Brief), and "Homo sapiens G-protein coupled receptor 97 (GPR97)" (GenBank accession number AY140959; see **Exhibit E** of the Appeal Brief); 3) That a murine sequence sharing 68% percent identity and 78% similarity at the amino acid level over the entire length of the described sequence is present in the leading scientific repository for biological sequence data (GenBank); 4) That the identified murine sequence has been annotated by different third party scientists *wholly unaffiliated with Appellants* as "Mus musculus Pb99 gene sequence" (GenBank accession number AF249738; see **Exhibit F** of the Appeal Brief); and 5) The murine protein, which is a homolog of the claimed human sequence, has been functionally characterized as a G-protein coupled receptor (see **Exhibit G** of the Appeal Brief). Given the scientific evidence of record, there can be no question that those skilled in the art would clearly believe that Appellants' sequence is a functional protein, as opposed to the assertion by the Examiner that "there is no sufficient and credible information that indicates the published sequence is a truly functional GPCR" (the Final Action at page 4). Therefore, Appellants point out in the Appeal Brief that the present case directly

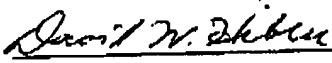
tracks Example 10 of the Revised Interim Utility Guidelines Training Materials (see Exhibit H of the Appeal Brief), which clearly establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility is not proper when a full length sequence (such as the presently claimed sequence) has a similarity score greater than 95% to a protein having a known function (such as the nearly 100% identity between the presently claimed sequence and the GPR97 sequences, as discussed above). Thus, as set forth in the Appeal Brief, as Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988) Appellants contend that the presently claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

Therefore, given that a specific assertion of utility is set forth by Appellants in the present Appeal Brief that has not been addressed by the Board on the record, Appellants respectfully request a rehearing of the present Appeal Brief, and for the Board to overrule the rejections of claims 1-3 and 6-8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

August 27, 2004

Date



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